AUG 2 8 2006

Cryocare CN2 System

K062175

510(k) SPECIAL PREMARKET NOTIFICATION SUMMARY

- **Device Trade or Proprietary Name:** Cryocare CN2 System
- **Common / Classification Name:** Cryosurgical unit and accessories
- **Class:** Class II
- **Regulation Number:** 878.4350
- **Product Code:** GEH
- **Labeling:**

  Federal (United States) Law restricts this device to sale by or on the order of a physician or licensed healthcare professional.

- **Predicate Device for Substantial Equivalence Comparison:**

  The Cryocare CN2 System Cryoprobe accessory is claimed to be substantially equivalent to the following Predicate Devices:

Manufacturer	Device Name	510-K Number	Decision Date
Cryomedical Sciences, Inc.	CMS Accuprobe®	K0982055	Sept. 08, 1998
Cryomedical Sciences, Inc.	CMS Accuprobe®	K0973190	Nov. 21, 1997
Cryomedical Sciences, Inc.	CMS Accuprobe®	K0964336	Mar. 20, 1997

- **Device Description:**

The Cryocare CN2 System consists of a compact, easy-to-operate console that delivers cold temperatures to targeted tissue (via connected Cryoprobes) and monitors temperatures in the surrounding tissue (via connected TempProbes). Near Critical Nitrogen (NCN) is utilized as the cryogenic medium. Circulating NCN avoids the 'vapor lock' potential of liquid N_2 devices since it is a transition fluid (nitrogen that is neither a liquid, nor a gas).

The Cryocare CN2 System has a fold-down LCD high-resolution display screen, a video printer for hard copy prints of the captured images and patient information, a CD-R/W drive for data storage and retrieval, an alphanumeric keypad and a remote keypad.

The Cryocare CN2 System can control up to four, single-use, disposable Cryoprobes and monitor up to four independent TempProbes. The console operates off standard 120/230 VAC (60/50 Hz) wall power and utilizes inert liquid nitrogen. An IBM compatible microprocessor serves as the host computer which performs all essential controls and monitoring tasks. Cryoprobe control is achieved via the keypad.

Associated accessories include the following:

1.) Cryoprobes that deliver cold temperatures to targeted tissue. Each Cryoprobe incorporates a thermocouple to measure internal Cryoprobe temperatures. Warm room

temperature nitrogen gas is used after the freezing process to thaw tissue. The patient contact Cryoprobe (an accessory item to the Cryocare CN2 System) is supplied as a Single use Sterile Disposable item. This probe attaches to a reusable Cryo-Hose, which in turn attaches to the Cryocare CN2 System.

2.) TempProbes to monitor temperatures in the surrounding tissue. The TempProbes are standard T-type thermocouples.

3.) A warming system for use in urological applications.

- **Indications for Use Statement:**

The Cryocare CN2 System has the **same intended use** as previously cleared for the predicate devices.
The Cryocare CN2 System is intended for use in open, minimally invasive or endoscopic surgical procedures in the areas in general surgery, urology, gynecology, oncology, neurology, dermatology, ENT, proctology, pulmonary surgery and thoracic surgery. The system is designed to freeze/ablate tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.
In addition, the system is intended for use in the following indications:

- General Surgery
  - Destruction of warts or lesions
  - Palliation of tumors of the oral cavity, rectum and skin
  - Ablation of leukoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemanglomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemanglomas, recurrent cancerous lesions
- Urology
  - Ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia
- Gynecology
  - Ablation of malignant neoplasia or benign dysplasia of the female genitalia
- Oncology
  - Ablation of cancerous or malignant tissue
  - Ablation of benign tumors
  - Palliative intervention
- Dermatology
  - Ablation or freezing of skin cancers and other cutaneous disorders
- Proctology
  - Ablation of benign or malignant growths of the anus or rectum
  - Ablation of hemorrhoids
- Thoracic Surgery
  - Ablation of arrhythmic cardiac tissue

- Ablation of cancerous lesions

- **Contraindications for Use**
  - There are no specific contraindications for the use of this device.

- Rationale for Substantial Equivalence

1. The Cryocare CN2 System patient interface accessory Cryoprobe and Cryo-Hose design is very similar to the predicate device [CMS Accuprobe accessory item already approved by the FDA].
2. The INTENDED USES and the OPERATING PRINCIPLES (i.e. Effectiveness) of the Cryocare CN2 System, Cryoprobe and Cryo-Hose accessory items are the *SAME* as the predicate device.
3. The OPERATIONAL FEATURES of the Cryocare CN2 System, Cryoprobe and Cryo-Hose accessory items are the *SAME* to those offered by the predicate device
4. The SAFETY FEATURES of the Cryocare CN2 System, Cryoprobe and Cryo-Hose accessory items are the *SAME* to those offered by the predicate device.

Therefore, in summary, the Cryocare CN2 System, Cryoprobe and Cryo-Hose accessory items are substantially equivalent to the identified predicate device accessory items that have previously been allowed for commercial distribution in the United States.

- **Safety and Effectiveness**

The Cryocare CN2 System complies with the ASTM "Standard Performance and Safety Specification for Cryosurgical Medical Instruments" [Designation: F 882-84 (reapproved 2002)] which reasonably assures the device is safe when used as directed for its prescribed intended use.

The Cryocare CN2 System does not raise any new issues of safety, effectiveness or performance of the device when compared to the existing predicate device.

• Conclusions

The data submitted in this 510(k) Premarket Notification, for the Cryocare CN2 System demonstrates that this device and Cryoprobe and Cryo-Hose accessory item is substantially equivalent with respect to the indications for use, operating principles, operational features, and safety features to the identified legally marketed predicate device. With the information provided, the safety and effectiveness of the product can be reasonably assured, and we believe that this device clearly meets the requirement for a "Substantial Equivalence" decision in accordance with the 510(k) guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

Endocare, Inc.
c/o Mr. Alden Kay
Senior Director Regulatory & Quality
201 Technology Drive
Irvine, CA 92618-2400

Re: K062175
Trade/Device Name: Cryocare CN2 System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II (two)
Product Code: OCL, GEH
Dated: July 31, 2006
Received: July 31, 2006

Dear Mr. Kay:

This letter corrects our substantially equivalent letter of August 28, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

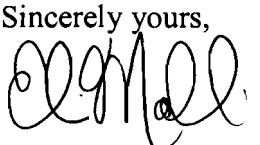
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K062175

Device Name: **Cryocare CN2 System**

Indications for Use (Page 1 of 2):

The Cryocare CN2 System is intended for use in open, minimally invasive or endoscopic surgical procedures in the areas in general surgery, urology, gynecology, oncology, neurology, dermatology, ENT, proctology, pulmonary surgery and thoracic surgery. The system is designed to freeze/ablate tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.

In addition, the system is intended for use in the following indications:

- General Surgery

  Destruction of warts or lesions
  Palliation of tumors of the oral cavity, rectum and skin
  Ablation of leukoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemanglomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemanglomas, recurrent cancerous lesions

Prescription Use X **(Per 21 CFR 801 Subpart D)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062775

Indications for Use

510(k) Number: K062175

Device Name: CryoCare CN2 System

Indications for Use (Page 2 of 2)

- Urology
  Ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia
- Gynecology
  Ablation of malignant neoplasia or benign dysplasia of the female genitalia
- Oncology
  Ablation of cancerous or malignant tissue
  Ablation of benign tumors
  Palliative intervention
- Neurology
  Freezing of nerve tissue in pain management/cryoanalgesia
- Dermatology
  Ablation or freezing of skin cancers and other cutaneous disorders
- Proctology
  Ablation of benign or malignant growths of the anus or rectum
  Ablation of hemorrhoids
- Thoracic Surgery
  Ablation of arrhythmic cardiac tissue
  Ablation of cancerous lesions

Prescription Use __X___ (Per 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062175